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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

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10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant's Name

09/684,066

Applicant(s)

RANGANATHAN ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicants' arguments, filed 10 April 2003, have been fully considered by they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-18 are currently pending in the application.

Applicant is reminded to please cancel claims 19-34 drawn to non-elected inventions.

Claims Rejections-35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the previous Office Action and reiterated below.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or

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absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) and e) In order to practice the claimed invention one of skill in the art must be able to identify positions in a polymer by accessing data and identifying positions by use of said algorithm. However, the methods of claims 1-18 are not enabled as the claims and the specification are lacking critical steps and information required for the performance of said methods. One of skill in the art would not be able to perform the invention as claimed and the steps as presently recited would not result in obtaining the desired information from the methods.

For example, in claims 1 and 10, what polymers are selected, on what basis are they selected, and how are they aligned in a multiple sequence alignment? The specification, at page 6, indicates that proteins are polymers that can be used, but is silent as to other polymers amenable to the method. For instance, are polyacrylamide polymers able to be used in this method? How would such non-protein polymers be aligned? Could free energy calculations be performed? The specification, at page 16, indicates that only protein sequences can be aligned, but is completely devoid of information as to how any other type of polymer is to be selected and aligned. Further, the claims do not set forth that the polymers to be aligned are from a single protein family or from related proteins. There is no requirement for a base level of similarity for the multiple sequence alignment such that one of ordinary skill in the art would be able to select appropriate sequences for use in this method. The specification, at page 17, indicates that "protein families" are used, but does not speak to how such families are correctly aligned.

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Once the polymer sequences are chosen and defined, it is unclear how the simple act of calculating the free energy of each position means anything without any cross comparison of free energy values between similar positions of other proteins in the family. A calculated value on its own, with no reference or baseline value tells one nothing of its significance. The claims do not have any such steps wherein values are compared and significance concretely defined and gained. The “identifying” step in claims 1 and 10 is devoid of any concrete active step(s) such that one of skill in the art would be able to follow such a step.

Claims 7-9 and 16-18 require “accessing data”, however, claims 1 and 10 do not require the acquisition and/or storage of any polymer data. It is unclear if only sequence data is needed or required or whether free energy data or some other types of data are utilized. The specification does not clearly address this issue. The specification indicates that the data can come from a variety of sources, but no particular type of format is required such that one of skill in the art would be able to obtain or provide such data.

Applicant argues that they are not claiming the creation of a Multiple Sequence Alignment (MSA) and go on to explain in detail how a MSA would be performed. It is acknowledged that MSA techniques are **well known** in the art and that Applicant is not claiming a method to perform an MSA. Applicant is claiming the identification of positions in a polymer family. Applicant has ignored the questions pertaining to the accession of data in terms of what polymers are utilized. Applicant does state that this method is applicable to **any** polymer, including drugs, chemical polymers etc. However, Applicant does not provide any specifics as to how this is performed and the specification is devoid of any information showing an

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alignment of chemical or other polymers and how these types of polymers would be used in said invention. The specification only points to a limited example using the PDZ **protein** family.

Applicant also argues that the Office has not pointed to any particular “critical step” or “concrete active step” and has therefore not met the burden for enablement. However, the fact remains that no comparison step is included such that significance of any one position can be ascertained.

One would look to the art to practice the invention. However, the art does not describe the claimed methods and without said steps known, it is not possible to practice said invention without undue experimentation.

b) and c) The specification provides working examples of using the particular method to calculate free energy for PDZ domains (page 26 and 27) that are known to be a family of small, evolutionarily well-represented protein binding motifs (page 25). The energetic profile of the fold family was determined and the energetic coupling function was determined. No specific steps to do this are outlined in the examples.

d) The invention is drawn to multiple sequence alignments to identify free energy and significant positions.

f) The skill of those in the art of bioinformatics is high.

g) The art is unpredictable.

h) The claims are broad because they are drawn to methods with all polymers and methods with minimal processing steps.

The skilled practitioner would first turn to the instant specification for guidance to practice the claimed methods. However, the instant specification does not provide specific guidance to

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practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art does not teach these methods. Finally, said practitioner would turn to trial and error experimentation to determine the limits and steps required. Such represents undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and dependent claims (2-9) remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims omit essential steps. (See M.P.E.P. 2172.01). The method of identifying one or more positions in a polymer family requires identification of the positions in a multiple sequence alignment. However, the steps taken in order to perform the identification portion of step (b) are not stated and it is unclear as to how this would be accomplished. Applicant asserts that there is a detailed description of how to perform step (b) on page 19, line 21-page 21, lines 20-28. These paragraphs describe the use of the algorithm, however, still do not provide information as to how to **identify** positions with significant conservation energy values. Is each position in the multiple sequence alignment assessed for significant energy conservation values? Are only proposed conserved regions utilized to identify possible significant conservation energy values? It would seem that what is meant is that conservation energy values are calculated and then upon calculation, positions that have significant values are identified (as in claim 10).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is

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(703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 26, 2003

Lori A. Clow, Ph.D.

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Lori A. Clow

MKZ
MARY K. ZEMAN
PRIMARY EXAMINER
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